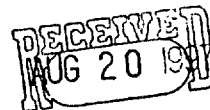


DELOIS L. SHELTON
OFFICE OF REGULATORY AFFAIRS
WEIDER NUTRITION GROUP, INC.
2002 SOUTH 5070 WEST
SALT LAKE CITY, UTAH 84104-4836
TELEPHONE (801) 975-5031
FACSIMILE (801) 972-2223

August 12, 1997



James Tanner, PhD

Acting Director, Division of Programs and Enforcement Policy

91 '97 SEP 19 P1:58

Office of Special Nutritionals

Center for Food Safety and Applied Nutrition

HFS-450

200 C Street SW

Washington DC 20204

Re: *Submission of Structure/Function Claims*

Dear Dr Tanner:

Enclosed are the structure/function claims for the following nutrients, as generated by Dr. Luke Bucci:

- 54312
- 1)✓ Schiff Vitamin C 500 mg and 1000 mg per serving
 - 2)✓ Schiff Vitamin A 1000 IU from fish liver oil
 - 3)✓ Schiff Prime Years Multivitamin and Mineral
 - 4)✓ Schiff Women's Daily Spectrum Multiple Vitamin, Mineral, Herbals
 - 5)✓ Schiff PCO+ Grape Seed Extract & Pycnogenol®
 - 6)✓ Muscle Tribe DHEA (Dehydroepiandrosterone)
 - 7) Schiff Vitamin B-6
 - 8) Schiff B Complex 50 Once Daily
 - 9)✓ Schiff Vitamin C with Rose Hips 500 count
 - 10)✓ Schiff Vitamin C with Rose Hips 100 count
 - 11)✓ Schiff Chelated Iron
 - 12)✓ Schiff Mega High II Multi-Vitamin/Mineral with Extra Iron and Zinc
 - 13)✓ Schiff Yeast Free B Complex 100 with Iron
 - 14)✓ Great American Nutrition Pain Free -- Glucosamine Hydrochloride
 - 15)✓ Schiff Hi-B Complex
 - 16) Schiff Vitamin B-1 (Thiamin)
 - 17)✓ Muscle Tribe Androstenedione
 - 18) Schiff Kelp with 225 mcg Iodine
- 54313
- 54314
- see odyssey letter file

7, 8, 16 & 18 not in submission
975-0162

LET 797

We welcome the opportunity to receive feedback from your office as we continue to interpret how to write structure/function claims as allowed by the Dietary Supplement Health and Education Act. There are some areas of overlap between nutrient functions or their effects on body structure and health claims. We anticipate that we will continue to fully comply with your interpretation of health claims.

Please feel free to contact me if you have further questions or comments.

Respectfully,

A handwritten signature in black ink, reading "De Lois L. Shelton". The signature is written in a cursive style with a large, stylized "D" and "S".

De Lois L. Shelton, Regulatory Compliance

cc: Dave Mastroianni, Luke R. Bucci

STRUCTURE / FUNCTION CLAIMS

RECEIVED
AUG 20 1997

NUTRIENT: Vitamin C

DATE: August 12, 1997
Document Name: sf01vitc.wpd

BY: Original (reviewed by LRB)

BRAND, CODE # & PRODUCT NAME(S): Schiff Vitamin C 10304(50t); 10306,10321(100t);
10307(250t); 10308(500t);
10313(60t); 10314(120t)

0292 '97 SEP 19 PM 36

NUTRIENT AMOUNT: 500 mg vitamin C per serving (one tablet)
(10304, 10306, 10321, 10307, 10308)
1000mg vitamin C per serving (one tablet)(10313,10314)

STRUCTURE/FUNCTION CLAIM:

Vitamin C is essential for formation of body protein and for building sound bones, teeth, skin, cartilage and capillaries.

REFERENCES:

1. Jacob, R.A., Vitamin C, in *Modern Nutrition in Health and Disease*, 8th ed., Shils, M.E., J.A. Olson, M. Shike, Eds., Lea & Febiger, Philadelphia, 1994, 432-448.
2. Englard, S. And S. Seifter, The biochemical functions of ascorbic acid. *Ann. Rev. Nutr.*, 1986; 6: 365-406.
3. Bender, D.A., Vitamin C, in *Nutritional Biochemistry of the Vitamins*, Cambridge University Press, Cambridge, 1992, 223-245.
4. Skelton, W.P. and N.K. Skelton, Deficiency of vitamins A, B and C: something to watch for, *Postgraduate Med.* 1990; 87(4): 293-310.

54312

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Vitamin A

AUG 20 1997

DATE: August 12, 1997
Document Name: sf01vita.wpd

BY: Original (reviewed by LRB)

PRODUCT: Schiff Vitamin A (100sg, 250sg) 10004

NUTRIENT AMOUNT: 10,000 IU from fish liver oil/softgel
029391 SEP 19 P1:58

STRUCTURE/FUNCTION CLAIM:

Vitamin A is a fat soluble vitamin that is necessary for new cell growth and healthy tissues and is essential for vision in dim light.

REFERENCES:

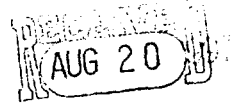
1. Olson, J.A., Vitamin A, retinoids, and carotenoids, in *Modern Nutrition in Health and Disease*, 8th ed., Shils, M.E., J.A. Olson, M. Shike, Eds., Lea & Febiger, Philadelphia, 1994, 287-307.
2. Bender, D.A., Vitamin A: retinol and β -carotene, in *Nutritional Biochemistry of the Vitamins*, Cambridge University Press, Cambridge, 1992, 19-26.

54312

Weider Nutrition Group
1960 South 4250 West
Salt Lake City UT 84104

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Multiple Vitamin/Mineral



DATE: June 5, 1997

BY: Luke R. Bucci, PhD

Document Name: sf07mult.wpd

0294 '97 SEP 19 P1:58
BRAND, CODE # & PRODUCT NAME(S): Schiff 11438 Prime Years Multivitamin and Mineral Especially Formulated for People 55 Years and Older (100sg)

NUTRIENT AMOUNT: see label listings (A, C, D, E, Bs, Ca, Mg, Fe, Zn, Cu, Mn, K, P, I, Cr, choline, inositol, methionine, PABA, bioflavonoids)

STRUCTURE/FUNCTION CLAIM:

Deficiencies in one or more essential vitamins and minerals are associated with detriments to immunity, cardiovascular integrity, fatigue, and overall well-being. Nutrient deficiencies may be caused by many factors, including lack of dietary intake or increased metabolic needs, and are common in the long-lived. Long-term vitamin supplementation has been associated with improved feelings of well-being and mood.

LR Bucci 6/18/97
Approved by / Date

REFERENCES:

1. Myrvik QN. Immunology and nutrition, in *Modern Nutrition in Health and Disease*, 8th ed., Shils ME, Olson JA, Shike M, Eds., Lea & Febiger, Philadelphia, 1994, 623-662.
2. Keusch GT. Nutrition and infection, in *Modern Nutrition in Health and Disease*, 8th ed., Shils ME, Olson JA, Shike M, Eds., Lea & Febiger, Philadelphia, 1994, 1241-1258.
3. Corman LC. Effects of specific nutrients on the immune response, *Med Clin N Am* 1985; 69:759-791.
4. Werbach MR. Atherosclerosis, in *Nutritional Influences on Illness*, 2nd ed., Third Line Press, Tarzana, CA, 1993, 57-102.
5. Werbach MR. Fatigue, in *Nutritional Influences on Illness*, 2nd ed., Third Line Press, Tarzana, CA, 1993, 283-289.

54312

Weider Nutrition Group
1960 South 4250 West
Salt Lake City UT 84104

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Women's Daily Spectrum Multiple Vitamin / Mineral / Herbals

AUG 20 1997

DATE: May 29, 1997
Document Name: sf01wds.wpd

0295 BY: Luke R. Bucci, PhD

BRAND, CODE # & PRODUCT NAME(S): Schiff 11496 Women's Daily Spectrum 120t

NUTRIENT AMOUNT: see label: full-spectrum of vitamins and minerals with herbal blend

STRUCTURE/FUNCTION CLAIM:

Schiff's Women's Daily Spectrum™ supplies essential vitamins and minerals, plus a unique balance of herbs and other nutritional factors, to help maintain good health and vitality. Women have found it to be particularly helpful when used as part of a program including exercise, stress management and wholesome dietary practices (Program included inside).

Included inside is a brochure which includes a step-by-step program to help you unwind, relax and better manage the everyday stressful moments of life. Dr. Lark outlines what foods to eat and those to avoid, suggests an exercise program designed to improve physical soundness and includes specific stress management techniques to relieve tension while improving mental fitness. If incorporated into one's lifestyle, this program can have a profound effect upon one's health and well-being.

The Women's Daily Spectrum™ was developed based upon the latest scientific findings in the area of nutrition and human health and reflects Dr. Lark's 10 year clinical experience with thousands of women patients.

LSR Bucci 6/5/97
Approved by / Date

REFERENCES:

1. Lark SM. *Anxiety and Stress Self Help Book*. Celestial Arts Publishing, Berkeley CA. 1996.
2. Lark SM. *The Menopause Self Help Book*. Celestial Arts Publishing, Berkeley, CA 1992.
3. Lark SM. *The Estrogen Decision Self Help Book*. Celestial Arts Publishing, Berkeley, CA, 1995.

54312

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Grape Seed Extract & Pycnogenol®

DATE: July 2, 1997

BY: Luke R. Bucci 10/16/96

Document Name: sf01pco+.wpd

AUG 20 1997

PRODUCT: Schiff PCO+ 12788, 12800, 12787, 12799

NUTRIENT AMOUNT: 50 or 100 mg per capsule 6 '97 SEP 19 P1:58

STRUCTURE/FUNCTION CLAIM:

PCO+™ is a 50/50 blend of proanthocyanidins from two natural sources, Grape Seed Extract and Pycnogenol® (maritime pine bark).

Powerful antioxidant activity in one highly effective formula.

REFERENCES:

1. Masquelier J, Michaud J, Laparra J, Dumon MC. Flavonoids et pycnogenols. *Int J Vit Nutr Res* 1979; 49:307-311.
2. Uchida, Edamatsu, Hiramatsu, Mori, Nanoaka, Nishioka, Niwa, Ozaki. Condensed tannins scavenge active oxygen free radicals. *Med Sci Res* 1987; 15:831-832.
3. Kuhnau J. The flavonoids. A class of semi-essential food components: their role in human nutrition. *Wrlld Rev Nutr Diet* 1976; 24:117-191.
4. Frenkel EN, Kanner J, German JB, Parks E, Kinsella JE. Inhibition of oxidation of human low-density lipoprotein by phenolic substances in red wine. *Lancet* 1993; 341:
5. Masquelier J. Plane extract with a proanthocyanidins content as therapeutic agent having radical scavenger effect and use thereof. US Patent No. 4,698,360, Oct. 6, 1987.
6. Ariga T, Hamano M. Radical scavenging action and its mode in procyanidins B-1 and B-3 from Azuki beans to peroxy radicals. *Agric Biol Chem* 1990; 54(10):2499-2504.
7. Bombardelli E, Morazzoni P. *Vitis vinifera* L. *Fitoterapia* 1995; 66:291-317.

54312

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Dehydroepiandrosterone (DHEA)

DATE: July 2, 1997

BY: LRB 10/10/96

Document Name: sf01dhea.wpd

PRODUCT: Muscle Tribe 51006 DHEA 60c 12780

NUTRIENT AMOUNT: 25 mg/cap

0301 '97 SEP 19 P1:58

AUG 20

STRUCTURE/FUNCTION CLAIM:

Dehydroepiandrosterone (DHEA) is produced naturally by the adrenal glands. DHEA functions as a buffer to help counteract adverse effects of stress. Unfortunately, as we get older, our body's production of DHEA declines significantly. DHEA supplements can restore deficient levels.

REFERENCES:

1. Regelson W, Kalimi MY, Dehydroepiandrosterone (DHEA) - a pleiotropic steroid. How can one steroid do so much? In *Advances in Anti-Aging Medicine*, Vol. 1, Klatz RM, Ed, Mary Ann Liebert, NY, 1996, 287-317.
2. Morales AJ, Nolan JN, Nelson JC, Yen SS, Effect of replacement dose of dehydroepiandrosterone in men and women of advancing age, *J Clin Endocrinol Metab*, 1994; 78:1360-1367.
3. Regelson W, Loria R, Kalimi M, Hormonal intervention: "buffer hormones" or "state dependency". The role of dehydroepiandrosterone (DHEA), thyroid hormone, estrogen and hypophysectomy in aging, *Ann NY Acad Sci*, 1988; 521:260-273.
4. Hornsby P, Biosynthesis of DHEAS by the human adrenal cortex and its age-related decline, *Ann NY Acad Sci*, 1995; 774:29-46.
5. Orentlich N, Brind J, Rizer R, Vogelmann J, Age changes and sex differences in serum dehydroepiandrosterone sulfate concentrations throughout adulthood, *J Clin Endocrinol Metab*, 1984; 59:551-554.
6. Yen SS, Morales AJ, Khorram O, Replacement of DHEA in aging men and women, *Ann NY Acad Sci*, 1995; 774:128-142.

54313

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Vitamin C

DATE: July 2, 1997

BY: Original (reviewed by LRB)

Document Name: sf03vitc.wpd

PRODUCT: Schiff Vitamin C with Rose Hips (500ct) 10308

NUTRIENT AMOUNT: 500 mg per serving (one tablet)

0300 '97 SEP 19 P1:58

STRUCTURE/FUNCTION CLAIM:

Vitamin C is essential for formation of body protein and or building sound bones, teeth, skin, cartilage and capillaries.

REFERENCES:

1. Jacob, R.A., Vitamin C, in *Modern Nutrition in Health and Disease*, 8th ed., Shils, M.E., J.A. Olson, M. Shike, Eds., Lea & Febiger, Philadelphia, 1994, 432-448.
2. Englard, S. And S. Seifter, The biochemical functions of ascorbic acid. *Ann. Rev. Nutr.*, 1986; 6: 365-406.
3. Bender, D.A., Vitamin C, in *Nutritional Biochemistry of the Vitamins*, Cambridge University Press, Cambridge, 1992, 223-245.
4. Skelton, W.P. and N.K. Skelton, Deficiency of vitamins A, B and C: something to watch for, *Postgraduate Med.* 1990; 87(4): 293-310.

54313

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Vitamin C

DATE: July 2, 1997

BY: Original (reviewed by LRB)

Document Name: sf03vitc.wpd

PRODUCT: Schiff Vitamin C with Rose Hips (100ct) 10304

NUTRIENT AMOUNT: 500 mg per serving (one tablet)

SEP 19 P1:58

STRUCTURE/FUNCTION CLAIM:

Vitamin C is essential for formation of body protein and or building sound bones, teeth, skin, cartilage and capillaries.

REFERENCES:

1. Jacob, R.A., Vitamin C, in *Modern Nutrition in Health and Disease*, 8th ed., Shils, M.E., J.A. Olson, M. Shike, Eds., Lea & Febiger, Philadelphia, 1994, 432-448.
2. Englard, S. And S. Seifter, The biochemical functions of ascorbic acid. *Ann. Rev. Nutr.*, 1986; 6: 365-406.
3. Bender, D.A., Vitamin C, in *Nutritional Biochemistry of the Vitamins*, Cambridge University Press, Cambridge, 1992, 223-245.
4. Skelton, W.P. and N.K. Skelton, Deficiency of vitamins A, B and C: something to watch for, *Postgraduate Med.* 1990; 87(4): 293-310.

54313 B

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Iron

DATE: February 19, 1996
Document Name: sf01iron.wpd

BY: Luke R. Bucci, PhD

PRODUCT: Schiff Chelated Iron (90t) 11215

NUTRIENT AMOUNT: 50 mg per serving (one tablet) P1:58

RECEIVED
AUG 20 1997

STRUCTURE/FUNCTION CLAIM:

Iron is necessary to form hemoglobin, the oxygen-carrying molecule in red blood cells, and to operate other enzymes involved in cell energy production. Deficiencies of iron may lead to fatigue, shortness of breath, and fewer red blood cells. Chelated forms of iron are generally absorbed well and are better tolerated.

REFERENCES:

1. Dallman, P.R., Iron, in *Present Knowledge in Nutrition*, 6th ed., Brown, M.L., Ed., International Life Sciences Foundation, Washington, D.C., 1990, 241-250.
2. Dallman, P.R., Biochemical basis for the manifestations of iron deficiency, *Annu. Rev. Nutr.* 1986: 6: 13-40.
3. Fairbanks, V.F., Iron in medicine and nutrition, in *Modern Nutrition in Health and Disease*, 8th ed., Shils, M.E., J.A. Olson, M. Shike, Eds., Lea & Febiger, Philadelphia, 1994, 185-213.

54313

Weider Nutrition Group
1960 South 4250 West
Salt Lake City UT 84104

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Multiple Vitamin/Mineral

AUG 20

DATE: June 5, 1997

BY: Luke R. Bucci, PhD

Document Name: sf06mult.wpd

0297 '97 SEP 19 P1:58

BRAND, CODE # & PRODUCT NAME(S):

Schiff 11428 Mega High II Multi-Vitamin /
Mineral with Extra IRON and ZINC (120sg)

NUTRIENT AMOUNT: see label listings (A, C, D, E, Bs, Ca, Mg, Fe, Zn, Cu, Mn, K, P, I)

STRUCTURE/FUNCTION CLAIM:

Deficiencies in one or more essential vitamins and minerals are associated with detriments to immunity, cardiovascular integrity, fatigue, and overall well-being. Nutrient deficiencies may be caused by many factors, including lack of dietary intake or increased metabolic needs. Long-term vitamin / mineral supplementation has been associated with improved feelings of well-being and mood.

LSR Bucci 6/18/97
Approved by / Date

REFERENCES:

1. Myrvik QN. Immunology and nutrition, in *Modern Nutrition in Health and Disease*, 8th ed., Shils ME, Olson JA, Shike M, Eds., Lea & Febiger, Philadelphia, 1994, 623-662.
2. Keusch GT. Nutrition and infection, in *Modern Nutrition in Health and Disease*, 8th ed., Shils ME, Olson JA, Shike M, Eds., Lea & Febiger, Philadelphia, 1994, 1241-1258.
3. Corman LC. Effects of specific nutrients on the immune response, *Med Clin N Am* 1985; 69:759-791.
4. Werbach MR. Atherosclerosis, in *Nutritional Influences on Illness*, 2nd ed., Third Line Press, Tarzana, CA, 1993, 57-102.
5. Werbach MR. Fatigue, in *Nutritional Influences on Illness*, 2nd ed., Third Line Press, Tarzana, CA, 1993, 283-289.
6. Manson JE, Stampfer MJ, Willett WC, Colditz GA, Rosner B, Speizer FE, Hennekens CH. A prospective study of vitamin C and the incidence of coronary heart disease in women,

54313

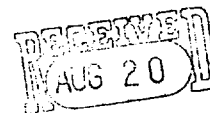
STRUCTURE / FUNCTION CLAIMS

NUTRIENT: B Complex Vitamins

DATE: June 5, 1997

BY: Luke R. Bucci, PhD

Document Name: sf06bcom.wpd



PRODUCT: Schiff 10132 Yeast Free B Complex 100 with Iron (50t)

NUTRIENT AMOUNT: B1, B2, Niacinamide, B6, Pantothenic acid, choline, inositol, PABA
all 100 mg
B12, Biotin = 100 mcg, folic acid = 400 mcg, per serving (one capsule)

STRUCTURE/FUNCTION CLAIM:

B Complex vitamins are required for many reactions in the body, especially breakdown of foods into energy. Maintenance of health of all body tissues relies on adequate B Complex vitamin status.

REFERENCES:

1. Machlin LJ. Ed. *Handbook of Vitamins. Second Edition, Revised and Expanded*, 2nd ed., Marcel Dekker, New York, 1991.
2. Combs GF. *The Vitamins. Fundamental Aspects in Nutrition and Health*, Academic Press, San Diego, 1992.

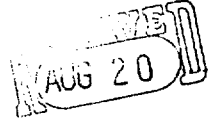
LR Bucci 6/18/97

54314

Weider Nutrition Group
1960 South 4250 West
Salt Lake City UT 84104

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: B Complex Vitamins



DATE: May 23, 1997

BY: Luke R. Bucci, PhD

Document Name: sf05bcom.wpd

0303 '97 SEP 19 P1:59

BRAND, CODE # & PRODUCT NAME(S): Schiff 10210 Hi-B Complex 250c

NUTRIENT AMOUNT: Thiamin, riboflavin, niacinamide, pyridoxine, folate, vitamin B12, biotin, pantothenate, choline, inositol, PABA from yeast and some added vitamins

STRUCTURE/FUNCTION CLAIM:

Hi-B Complex contains some natural sources of B-complex vitamins from high potency primary and brewer's yeasts, with B-12. B vitamins assist in the release of energy from foods.

LSR Bucci 5/23/97
Approved by / Date

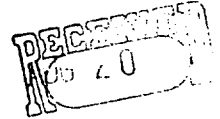
REFERENCES:

1. Machlin LJ, Ed. *Handbook of Vitamins. Second Edition, Revised and Expanded*, 2nd ed., Marcel Dekker, New York, 1991.
2. Combs GF. *The Vitamins. Fundamental Aspects in Nutrition and Health*, Academic Press, San Diego, 1992.

54319

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Androstenedione



DATE: July 28, 1997
Document Name: sf01andr.wpd

BY: Luke R. Bucci, PhD

0304 '97 SEP 19 P1:59

BRAND, CODE # & PRODUCT NAME(S): Muscle Tribe 52369 Androstenedione

NUTRIENT AMOUNT: 100 mg Androstenedione per 2 caps

STRUCTURE/FUNCTION CLAIM:

Androstenedione is a normal precursor for production of testosterone found in humans. MUSCLE TRIBE'S™ Androstenedione is a patented blend of pure androstenedione, Green tea extract and zinc. The green tea extract and zinc are added to help minimize the potential side effects estrogen may have on the male bodybuilder. Each capsule contains 50 mg of the best androsetnedione available today.

LSR Bucci 7/28/97
Approved by / Date

REFERENCES:

1. Maresh VB, Greenblatt RB. The in vivo conversion of dehydroepiandrosterone and androstenedione to testosterone in the human. *Acta Endocrinol* 1962; 41:400-406.
2. Longcope C, Fineberg SE. Production and metabolism of dihydrotestosterone in peripheral tissues. *J Steroid Biochem* 1985; 23:415-419.
3. Belisle S, Lehoux JG, Brault J. Metabolism of androstenedione in human pregnancy: use of constant infusion of unlabeled steroid to assess its metabolic clearance rate, its production rate, and its conversion into androgens and estrogens. *Am J Obstet Gynecol* 1980; 136:1030-1035.
4. Miller AL. Benign prostatic hyperplasia. Nutritional and botanical therapeutic options. *Alt Med Rev* 1996; 1:18-25.
5. Fahim MS, Fahim Z, Der R, Harman J. Zinc treatment for the reduction of hyperplasia of the prostate. *Fed Proc* 1976; 35:361.
6. Komori A, et al. Anticarcinogenic activity of green tea polyphenols. *Jpn J Clin Oncol* 1993; 23:186-190.

54319